K071588

510(k) Summary

NOV 2 6 2007

Submitter:	NOUVAG AG St. Gallerstrasse 23-25 CH-9403 Goldach Switzerland
Contact Person:	Benno Frei Technical Director, New Product Development Phone 0041 71 846 66 00 Fax 0041 71 845 35 36
Date Summary Prepared:	May 31, 2007
Device Name:	
Proprietary Name	Dispenser DP 20
Common Name	Infiltration Pump
Classification Name	Infusion Pump (per 21 CFR section 880.5725)

Identification of the predicate device or legally marketed device or devices to which substantial equivalence is being claimed:

Product:	PSI-TEC Peristaltic Infiltration Pump
Manufacturer	Byron Medical, Incorporated
510(k) Number	K040149
Product:	Wells Johnson Infusion System, Model 20-6000-00
Manufacturer	Wells Johnson
510(k) Number	K991437

Device Description:

The principle of operation and technology incorporated in the Dispenser DP 20 are equivalent to peristaltic irrigation systems, which use peristalsis-type action to move fluid through a tube by alternating mechanical squeezing of fluid-filled tubing with a roller.

As with all peristaltic pumps, the Dispenser DP 20 contacts only the tubing and never directly contacts the fluid, thus fluid sterility cannot be compromised by the pumping action.

Sterility:
Tubing set; disposable with plug-in cannula, sterile, length 4 m

Intended use of the Devices:

The Dispenser DP 20 is intended for the general surgical fluid irrigation and infiltration under the direct control of a physician. The infiltration pump is not intended for intravascular infusion of fluids.

Statement of how the technological characteristics of the device compare to those of the predicate or legally marketed device:

The principle of operation and technology incorporated in the NOUVAG Dispenser DP 20 are similar to other irrigation devices with the function to deliver fluid with a roller, which the FDA has founded to be substantially equivalent to pre-amendment devices as outlined above.

Brief summary of nonclinical tests and results:

The Dispenser DP 20 has been designed and tested to applicable safety standards. The Dispenser DP 20 does not raise any new issues of safety, effectiveness, or performance of the product

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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NOUVAG AG.
C/O Mr. Erich Forster
Regulatory Consultant
INTRATest Systems GmbH
Reusswehrstrasse 1
CH-5412 Gebenstorf
SWITZERLAND

Re: K071588
Trade/Device Name: Dispenser DP 20
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: II
Product Code: FRN
Dated: November 15, 2007
Received: November 19, 2007

Dear Mr. Forster:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

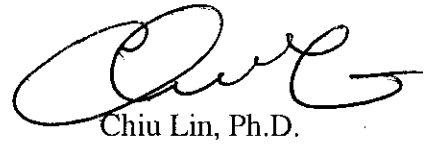
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K071588

Device Name: Dispenser DP 20

Indications for Use:

The Dispenser DP 20 is intended for the general surgical fluid irrigation and infiltration under the direct control of a physician.
The infiltration pump is not intended for intravascular infusion of fluids.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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